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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/041,975	03/13/1998	MARC ALIZON	2356.0011-06	4167

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/041,975

Applicant(s)

ALIZON ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,25,44-46 and 48-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 25, 44-46, and 48-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Serial No.: 09/041,975
Applicants: Alizon, M., et al.

Docket No.: 2356.0011-06
Filing Date: 03/13/98

Detailed Office Action

Status of the Claims

Claims 23, 25, 44-46, and 48-56 are currently under examination.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 25, 44-46, and 48-56 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims have been amended to include a limitation specifying that the HIV-1 variant is capable of hybridizing under stringent conditions across the entire LAV_{MAL} genome set forth in Figure 7. However, the claim allows for genetic variation up to ~22% in the env coding region. It is not readily manifest if nucleotide sequences displaying this degree of genetic unrelatedness would be capable of hybridizing under to recited reaction conditions. Appropriate clarification and correction are required.

Claims 23, 25, 44-46, 51, and 53-56 are also vague and indefinite for referencing the term "direct sequence repeat". The

claims fail to set forth any meaningful nucleotide or amino acid sequence structural limitations that clearly set forth the metes and bounds of the patent protection desired. Thus, it is not readily manifest which sequences are encompassed by the claim limitations.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 25, 44-46, and 48-56 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Rochester*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (C.A.F.C. 2004). The amended claims are directed toward purified HIV-1 variants displaying a certain amount of genetic unrelatedness at the nucleotide sequence level (e.g., ~10-12% in Gag; ~5-8% in Pol; ~21-22% in Env). Additional functional limitations were also provided including some of the following: 1) The variant binds to antibodies present in AIDS patient sera; 2) The variant displays the canonical genomic organization 5'-LTR-gag-pol-vif-vpr-tat-rev-vpu-env-nef-LTR-3'; 3) The variant hybridizes to a full-length

LAV_{MAL} genomic cDNA; and 4) The variant has at least one restriction site as set forth in Figure 1.

As previously set forth, the crux of the statutory requirement governing written description is whether one skilled in the art, familiar with the practice of the art at the time of the filing date, could reasonably have found the later claimed invention in the specification as filed. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983). *In re Wilder*, 736 F.2d 1516, 1520 222 U.S.P.Q. 349, 372 (Fed. Cir. 1984, cert. denied, 469 U.S. 1209 (1985)). *Texas Instruments, Inc. v. International Trade Comm'n*, 871 F.2d 1054, 1063, 10 U.S.P.Q.2d 1257, 1263 (Fed. Cir. 1989). Moreover, the courts have stated that the evaluation of written description is highly fact-specific, and that broadly articulated rules are inappropriate. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976). *In re Driscoll*, 562 F.2d 1245, 1250, 195 U.S.P.Q. 434, 438 (C.C.P.A. 1977). It is also important to remember that the true issue in question is not whether the specification enables one of ordinary skill in the art to make the later claimed invention, but whether or not the disclosure is sufficiently clear that those skilled in the art will conclude that the applicant made the invention having the specific claim limitations. *Martin v. Mayer*, 823 F.2d 500, 505, 3 U.S.P.Q.2d 1333, 1337 (Fed. Cir. 1987).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor has **possession** of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and

formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1996).

The issue raised in this rejection is whether or not the disclosure supports the broad genus of HIV-1 variants currently being claimed. As previously set forth, and contrary to applicants' assertions, the disclosure only describes the molecular cloning and characterization of a single novel HIV-1 isolate, designated LAV-1_{MAL} or HIV-1_{MAL}. For example, the specification clearly states (bridging paragraph, pp. 2 and 3) that "a new virus has been discovered that is responsible for diseases clinically related to AIDS and that can be classified as a LAV-1 virus but that differs genetically from known LAV-1 viruses to a much larger extent than the known LAV-1 viruses differ from each other. The new virus is basically characterized by the cDNA sequence which is shown in Figures 7A to 7I, and this new virus is hereinafter generally referred to as LAV_{MAL}." The disclosure provides a

restriction map for a molecular clone of HIV-1_{MAL} (see CHARACTERIZATION AND MOLECULE CLONING OF AN AFRICAN ISOLATE, pp. 7 and 8, and Figure 1). The complete nucleotide sequence and deduced amino acid sequence of this clone were ascertained (see Figure 7). The nucleotide sequence and deduced amino acid sequence of this novel isolate were compared to other known HIV-1 isolates (e.g., BRU, ELI, and ARV-2) (see Figures 1B-4 and 6). Based upon this comparison the inventors made three general conclusions. First, it was noted (specification, p. 10) that "the protein sequences of the LAV_{ELI} and LAV_{MAL} are more divergent from LAV_{BRU} that are those of HTLV-3 and ARV-2 (FIG. 4A)". Second, applicants reported that the env gene is more variable than the gag and pol genes. Third, it was reported that the divergence between LAV_{ELI} and LAV_{MAL} was comparable to that between LAV_{BRU} and each of the isolates. Thus, the skilled artisan would reasonably conclude that applicants have identified, cloned, and characterized a novel HIV-1 isolate designated MAL. The skilled artisan would also reasonably conclude that applicants ascertained the genetic relatedness of this particular isolate to other known HIV-1 isolates such as HIV-1 ELI, BRU, and ARV-2. However, the skilled artisan would not reasonably conclude that applicants were in possession of any other HIV-1 variants, particularly one with the claimed limitations. The disclosure fails to provide any other molecular clones and their attendant nucleotide/amino acid sequences. The disclosure fails to identify the isolation, characterization, and nucleotide sequence of other variant HIV-1 MAL isolates. Thus, the applicants were clearly not in possession of the claimed subject matter at the time of filing and the claim language clearly represents an unwarranted attempt to capture subject matter that was clearly not invented by the applicants.

It should be further noted that the Lentivirinae, particularly

HIV-1, exists as a quasispecies (Li et al., 1991; Groenink et al., 1991; Daniels et al., 1991; Delwart et al., 1994). Because of the infidelity of the reverse transcriptase (RT) numerous viral copies are generated with different genotypic/phenotypic characteristics. Thus, the skilled artisan cannot predict *a priori* the nucleotide sequence of any given isolate before it is cloned and characterized. In fact, the skilled artisan would expect multiple molecular clones from the same individual to display considerable genetic heterogeneity. Thus, the skilled artisan cannot readily envisage the structure of any given variant. Moreover, many of the limitations set forth in the claim language fail to distinguish LAV_{MAL} variants from other HIV-1 variants. For instance, antibodies that bind to MAL will also bind to other HIV-1 isolates. Although the claims discuss antibodies that specifically bind to MAL, there is no description or discussion of antibodies in patient sera that recognize only MAL and not other isolates. Limitations directed toward the canonical genetic organization of LAV_{MAL} are not further limiting because all HIVs display the same genetic organization: 5'-LTR-gag-pol-vif-vpr-tat-rev-vpu-env-nef-LTR-3'. Finally, even at the claimed degrees of genetic unrelatedness, the claims encompass an inordinate number of species.¹ Clearly, applicants were not in possession of a representative number of species at the time of filing to support the full-breadth of the genus encompassed by the claim language.

¹ For instance, the Gag region alone could generate 1.5×10^{136} variants. This calculation is based upon 10% genetic variation across the entire Gag protein (505aa) and substitution with any one of the 19 naturally occurring amino acids. The Pol region alone could generate 1.1×10^{177} variants. This calculation is based upon 6% genetic variation across the entire Pol protein (1002aa) and substitution with any one of the 19 naturally occurring amino acids. The Env region alone could generate 1.7×10^{423} variants. This calculation is based upon 21% genetic variation across the entire Env protein (859aa) and substitution with

Response to Arguments

As previously set forth, Applicants' amendments to the claim language fail to provide sufficient structural limitations that would lead the skilled artisan to conclude that applicants were in possession of the broad genus of HIV-1 variants. It is clear from the specification that applicants only describe the molecular cloning and characterization of a single HIV-1 variant designated MAL. The disclosure does not detail the cloning and characterization of any other isolates. The HIV-1 proviral genome is close to 10 kb in length. Thus, even minor variations in amino acid sequence identity can have profound effects on the replicative and immunologic properties of the virus. However, the disclosure fails to provide any detailed structure guidance pertaining to those regions that are critical for retaining the activity of any particular viral gene product. Applicants continue to argue that the specification provides adequate support for the concept of MAL variants (e.g., see p. 3, l. 4-8). This passage states that "Also in accordance with this invention, variants of the new virus are provided. The RNAs of these variants and the related cDNAs derived from said RNAs are hybridizable to corresponding parts of the cDNA of LAV_{MAL}." The generic reference to other variants is insufficient to put applicants in possession of the claimed isolates/variants/strains. The courts have concluded that a clear lack of adequate written description arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a

any one of the 19 naturally occurring amino acids.

genus because it would not reasonably lead those skilled in the art to any particular species. Thus, simply specifying that variant nucleic acids hybridize to LAV_{MAL} do not provide any additional detailed structural guidance. The HIV genome is large (~9.5kb) and complex and encodes a number of different structural, regulatory, and ancillary gene products. Within any given isolate or variant, there will be conserved regions and non-conserved regions. However, nucleic acids corresponding to conserved regions will hybridize to MAL variants, as well as, other unrelated variants. Thus, this particular reference would not lead the skilled artisan to any particular MAL variant.

Applicants further argue that sufficient structural and functional criteria have been included in the claim language and that said criteria adequately define the genus of MAL variants. The examiner does not concur with this assessment. First, limitations (i) and (ii) fail to provide any significant structural information since both MAL variants and non-MAL variants will contain common conserved epitopes (i.e., Gag, Pol, and Env) that are recognized by sera from AIDS patients. Thus, simply ascertaining antigen-antibody binding employing polyclonal antisera will not provide any meaningful structural information. A more useful limitation might involve a panel of several MAL-specific and -non-specific monoclonal immunological reagents directed against known epitopes.

Limitation (iii) also suffers from the same short-comings in the sense that it fails to provide any meaningful structural information vis-a-vis MAL variants. All replication-competent human immunodeficiency proviruses (type 1) contain the following generic genomic structure: 5'-LTR-gag-pol-vif-vpr-tat-rev-vpu-env-nef-LTR-3'. However, this limitation fails to provide any guidance pertaining to the actual nucleotide or amino acid sequence of any

portion of the genome. Thus, it does not provide any further significant structural limitations.

Furthermore, limitation (iv) also suffers from the same problems. Restriction fragments and oligonucleotide probes derived from the parental MAL isolate would still hybridize to shared conserved regions (i.e., Gag, Pol, Env) in the viral genome under a variety of hybridization conditions, including those of a stringent nature. For instance, an oligonucleotide probe derived from nucleotides 569-599 of the env region (see Figure 3F-1) would detect isolates MAL, ARV-2, BRU, IIIB, and ELI. Thus, no meaningful deductions could be made pertaining to the actual isolate detected. A more useful criterion might include a panel of specific- and non-specific MAL probes.

Additional limitations were provided specifying that the variant encodes a portion of the MAL Env. This criterion suffers from the same type of deficiencies in the sense that including a portion of the MAL Env does not provide any guidance pertaining to the nucleotide and/or amino acid sequence of the other regions of the genome (e.g., LTR, gag, pol, vif, vpr, nef, tat, rev, etc.). Therefore, the aforementioned limitations in concert or alone, fail to provide sufficient structural data that would lead the skilled artisan to readily envisage the nucleotide and amino acid structure of any given MAL "variant".

Finally, applicants argue that similar claims were allowed in U.S. Patent No. 5,567,703 [sic-5,567,603]. Applicants are reminded that each application is evaluated on its own merits. Patentability to others is immaterial in the instant application.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this

section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 23, 25, 43-46, and 48-56 stand rejected under 35 U.S.C.

§ 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Myers et al. (1990). Applicants' again contend that the claims are fully supported by the disclosure and are entitled to the benefit of priority to earlier filed U.S. and French applications. As previously set forth, and contrary to applicants' assertion, this application clearly fails to provide an adequate written description of the claimed invention and priority cannot be extended under 35 U.S.C. § 119 or 120. Accordingly, the following art rejection is proper and hereby maintained. Myers et al. (1990) provide the complete nucleotide sequence of a novel purified HIV-1 isolate designated Z2Z6. This isolate is genetically related to the HIV-1 isolates ELI and MAL and appears to be only distantly related to the isolates BRU, IIIB (or HXB2), and ARV-2 (SF-2). Nucleotide sequence and amino acid analysis demonstrated that this isolate appears to vary from the aforementioned prototypical isolates BRU, IIIB, and ARV-2 by at least 3.4%, 3.1%, and 13.0% in the *gag*, *pol*, and *env* coding regions, respectively. Thus, this isolate appears to meet all the limitations of the claimed invention. Moreover, because of the close genetic relatedness between Z2Z6 and the isolates ELI and MAL, one of ordinary skill in the art would reasonably expect nucleic acid probes and antibodies specific for MAL to also recognize Z2Z6 nucleic acids and antigens.

Finality of Office Action

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until

after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908.

The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

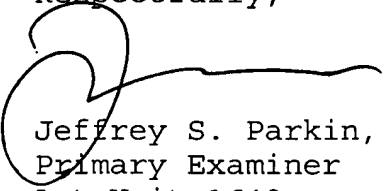
Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see

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<http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

26 December, 2006